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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,672	01/21/2004	David S. Garvey	102258.137US1	1938

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,672	GARVEY ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-8 and 10-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8 and 10-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of 09/20/06 is acknowledged. Claims 6-8 and 10-25 are pending and examined on the merits as drawn to methods of treating *any* gastrointestinal disorder using a compound of formula II (e.g. SPM 3672, 4757, 5185, 5186, 6372). An updated search has been conducted, as well as a more thorough review of the claims/specification, which have led to new rejections not originally of record and omitted by mistake. Due to the new grounds of rejection under 35 USC 102(a), 112 1st, and Double Patenting the present action is made NON-FINAL.

In the previous action, potentially allowable subject matter was indicated, noting "claims 6-25, as drawn to the respective methods of treating gastrointestinal disorders using compounds of formula II (notwithstanding the outstanding rejections as to Compound SPM 3672 under section 103 above and the 112 1st scope of enablement as to "prevention" and objection), are not reasonably taught or suggested by the prior art of record. Were the rejections successfully argued or the claims amended to overcome the rejections, the claims would like receive favorable consideration." The above indication has been removed, based on the new rejections of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 6-8 and 10-25 rejected under 35 U.S.C. 102(e) as being anticipated by Khanapure et al. (US 6,706, 724 and US 2002/0119977 (publication of '724).

Khanapure et al. teach a method of treating gastrointestinal disorders comprising the use of nitric oxide donors; such as SPM 3672, 5185, 5186 and variants thereof (US '724 claims 34-37 and 5, in view of para's 2, 6, and 10 of specification (see corresponding US '977 publication for para #'s)).

The applied reference has at least one common inventor (Garvey) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The above reference, like the present claims, is drawn to methods of treating any GI disorder. Neither the above reference nor the present specification is deemed so broadly enabled with the limited compositions disclosed therein. Thus, a scope of enablement rejection under 35 USC 112 1st is also made below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Daugan et al. (US 6,143,746), is maintained for the reasons of record. Applicant has cancelled the recitation of "decreasing the recurrence of an ulcer" using SPM 3672, but has not traversed the remainder of the rejection; namely argued why Daugan et al. does not also teach treating/improving e.g. an other gastrointestinal disorders such as peptide ulcers (e.g. treating/improving any gastrointestinal property of a COX-2 selective inhibitor or improving any gastroprotective). Thus, the rejection has been maintained (and is included below for ease of continuity of record).

Daugan et al. teach a composition comprising a compound of formula II (namely SPM 3672) for the treatment of various diseases, including peptide ulcers (claims 1 and 12); as well as compositions with carriers (col. 9, line 35).

If not expressly taught therein, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat gastrointestinal disorders such as peptide ulcers, using a compound of formula II (SPM 3672) in Daugan et al., because the references expressly teaches that peptic ulcers, a known gastrointestinal disorder, is the one of the disorders contemplated for being treatable using a compound of SPM 3672. One of ordinary skill in the art would have been motivated to treat peptide ulcers, and other related gastrointestinal disorders,

using SPM 3672, based on the teachings of Daugan et al. (It is noted that the reference *does not appear to provide motivation for the use any other compounds* of formula II, in the methods of treating gastrointestinal disorders such as peptic ulcers, other than SPM 3672, the only compound clearly identified in the compound search of the reference).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-8 and 10-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-37 and 5 of U.S. Patent No. 6,706,724 (corresponds to US Publication 2002/0119977). Although the conflicting claims are not identical, they are not patentably distinct from each other because '724 teach a method of treating gastrointestinal disorders comprising the use of nitric oxide (N.O.) donors (claims 34-37 and 5). The claims being read in light of the specification, para's 2, 6, and 10 (corresponding to US '977 publication) teach that N.O. donors include SPM 3672, 5185, 5186 and variants thereof. It would have been obvious to one of ordinary skill in the art at the time of the invention to use any known SPM variants at the time of the invention for use in the present invention, merely as matter of routine optimization, depending on the desired effect (all of which '724 guides the practitioner as to).

Claim Rejections - 35 USC § 112 1st Scope

Claims 6-8 and 10-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the SPM variants to treat certain gastrointestinal disorders (e.g. peptide ulcers); does not reasonably provide enablement for treating any GI disorder using compositions comprising the present SPM's or variants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...".

> The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for a method of using SPM's and virtually any variant thereof to treat any GI disorder.

The nature of the invention: The invention is described above.

The state of the prior art and the predictability or lack thereof in the art:

Daugan et al. describes that SPM 3672 may be used to reduce peptide ulcers (as cited above under 103).

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). Applicant's own specification also provides asserted uses of SPM's and variants thereof, with no corresponding tests or tables to validate that these SPM's may be used to treat any GI disorder, let alone peptide ulcers (which the prior art of record provides enablement for).

The breadth of the claims and the quantity of experimentation needed: The claims are drawn broadly to the use of SPM's and virtually any variant thereof to treat any GI disorder. With the complexity of compound-receptor binding, and whether these compounds are actually able to bind to any and all receptors responsible for any GI disorder, there is substantial variability among what, if any, of these compounds actually work to effectively treat any GI disorder, other than peptide ulcer. Absent sufficient teachings in the specification or art sufficient to overcome the teachings of unpredictability in the art as to enablement on the use of any SPM or variant thereof, to treat any GI disorder, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 11/25/2006

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PATENT EXAMINER
ART UNIT 1654

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